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09/813,292	03/21/2001	Borge Kringelum	030307- 0197	1783
22428	7590	06/28/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/813,292	KRINGELUM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruth A. Davis	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's Request for Continued Examination submitted May 5, 2004 has been received and entered into the case. Accordingly, the amendment, arguments, and declaration submitted on March 5, 2004 have been entered into the case. Claim 27 is added, claims 1 – 27 are pending and have been considered on the merits. All arguments and the declaration have been fully considered.

#### ***Claim Rejections - 35 USC § 112***

1. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 7, 11, 17 – 22 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing.

Applicant claims a method for supplying a starter culture with a consistent quality, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) is improved by (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets having a quality to inoculate a medium, (c) inoculating the subsets directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the divided subsets, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least  $10^8$  CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The

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amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$ CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of

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routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

5. Claims 1 – 7, 11, 17 – 22 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak.

Applicant claims a method for supplying a starter culture with a consistent quality, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

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wherein step (i) is improved by (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets having a quality to inoculate a medium, (c) inoculating the subsets directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the divided subsets, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least  $10^8$  CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

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Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the culture medium comprising skimmed milk. However, Czulak teaches a method of inoculating milk with a fat content of 0.3 – 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Czulak to use a



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culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

The above references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

6. Claims 1 – 11, 17 – 22 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) is improved by (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets having a quality to inoculate a medium, (c) inoculating the subsets directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the divided subsets, the starter cultures have a consistent quality.

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The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least  $10^8$  CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The stock inoculum material or subset is liquid, frozen, or dried; the frozen inoculums are first thawed before inoculation; and the subsets are combined with an aqueous medium to obtain a suspension before cultivating. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$ CFU/g, harvesting the starter cells

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and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the methods wherein the inoculums are liquid, frozen or dried; wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium before inoculating into the culture medium. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to do so as a matter of routine practice. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum and/or subset cultures as a liquid, frozen or dried,

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thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

The references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

7. Claims 1 – 7, 11 – 22 and 24 - 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Vandenberg and Matsumiya.

Applicant claims a method for supplying a starter culture with a consistent quality, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) is improved by (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets having a quality to inoculate a medium, (c) inoculating the subsets directly into the medium;

and wherein when steps (ii) -- (iii) are repeated with the divided subsets, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate

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at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least  $10^8$  CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The stock inoculum is supplied in a sealed enclosure, made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile and a cellulose derivative; a metal foil; has a content of at least 0.01 liters; has an outlet for connecting to the culture medium container, which allows for aseptic inoculation.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a

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culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach that the stock inoculum is provided in a sealed enclosure as claimed. However, Vandenberg teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such containers, Matsumiya discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the claimed invention, one of ordinary skill in the art would have been motivated

to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh and Maysumiya. Furthermore, it would have been well within the purview of one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture as a matter of routine practice.

The references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

8. Claims 1 – 7, 11, 17 – 22 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak and Lizk.

Applicant claims a method for supplying a starter culture with a consistent quality, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) is improved by (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets having a quality to inoculate a medium, (c) inoculating the subsets directly into the medium;

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and wherein when steps (ii) – (iii) are repeated with the divided subsets, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least  $10^8$  CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$ CFU/g, harvesting the starter cells



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and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein each of the named organisms are used.

However, at the time of the claimed invention, each of the claimed organisms were well known and used in the art as sources of starter cultures. In support, Czulak teaches a method of

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inoculating milk with Lactobacillus and Streptococcus cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

9. Claims 1 – 7, 11 and 17 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Rimler and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) is improved by (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets having a quality to inoculate a medium, (c) inoculating the subsets directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the divided subsets, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least  $10^8$  CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a

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rate of 0.1%, the medium after step (c) contains at least  $10^5$  CFU/g, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products such as enzymes, active substances, polysaccharides or amino acids; or produce desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

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Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein the starter cells are used in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler teaches a method of propagating starter cells of *Haemophilus* in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured

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and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

### *Response to Arguments*

Applicant argues that the references do not teach a consistent quality, that the references are concerned with the method of using the cultures, not a method of producing the cultures, and that the references choose the best quality resulting from the methods, not a method that produces consistent quality. Applicant additionally provides a declaration with evidence pointing to commercial success of the claimed method.

However, these arguments fail to persuade because while the references may teach methods of using the cultures, the methods of production are also disclosed. Regarding the declaration, the arguments and evidence are not commensurate in scope with the claimed methods. Specifically, the standards of comparison are not equivalent, making the data unclear. The numbers of batches produced by each method are not the same making the percent approval comparison unclear, the percent approval of the claimed method does not appear to exhibit unexpected advantages over the conventional methods, and the percent approval is higher in some starter cultures using conventional methods rather than the method of the invention

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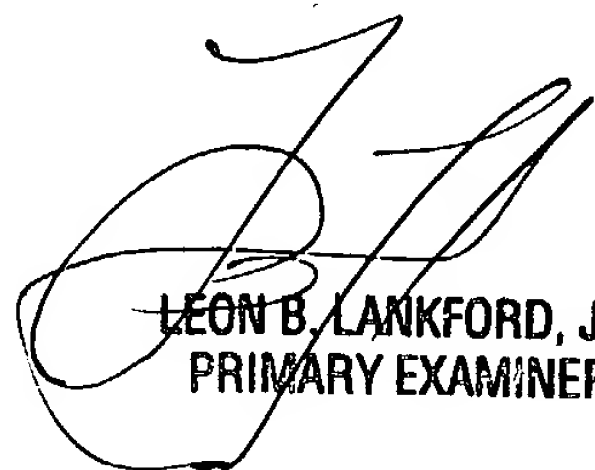
(specifically when using R-603). While the evidence appears to indicate practicing the claimed method with *B. bifidum* imparts an unexpected, higher approval rate, it is without certainty since the evidence is not standardized. Moreover, the claims stand rejected for these and the reasons stated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad  
June 22, 2004.



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER